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APPLICATION NO	PU DIC DATE	FIDET MANAED DIVENTOR	ATTORNEY DOCKET NO	CONFIDMATIONANO
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,701	01/29/2004	David K. Kovalic	38-21(53535)B	6459
27161 MONSANTO C	7590 01/25/200 COMPANY	EXAMINER		
800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	
SHORTENED STATUTORY	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		01/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

•		Application No.	Applicant(s)			
Office Action Summary		10/767,701	KOVALIC ET AL.			
		Examiner	Art Unit			
		Shubo (Joe) Zhou	1631			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)[[	Responsive to communication(s) filed on 7/2	24/06 11/2/06				
•	This action is <b>FINAL</b> . 2b) This action is non-final.					
·—	ince this application is in condition for allowance except for formal matters, prosecution as to the merits is					
ٽ/ <b>ٽ</b>	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
-	4) Claim(s) 2 and 4-7 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
·	Claim(s) is/are allowed.					
	6)⊠ Claim(s) <u>2 and 4-7</u> is/are rejected.					
•	Claim(s) is/are objected to.	Var alastian requirement				
اــا(ە	Claim(s) are subject to restriction and	or election requirement.				
Application Papers						
9) The specification is objected to by the Examiner.						
10)	The drawing(s) filed on is/are: a) a	ccepted or b) objected to by the	Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119		·			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate			
3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:						
Paper No(s)/Mail Date						

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#### **DETAILED ACTION**

#### **Amendments**

1. Applicants' amendment to the title, filed 11/2/06, and the amendments to the claims, filed 7/24/06, have been entered.

However, the amendments to the specification, filed 7/24/06, have not been entered as noted in the Notice of Noncompliant Amendment mailed 10/2/06. It should be pointed out that the mailing of the noncompliant letter of 10/2/06 means that the entire amendment to the specification, filed 7/24/06, has not been entered as the Office cannot enter in part of an amendment to the specification. In response to the Notice of Noncompliant Amendment mailed 10/2/06, applicant only provided amendment to the title on 11/2/06.

Applicant's arguments filed 7/24/06 in response to the previous Office action mailed 4/24/06 have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated from the previous Office action or newly added, necessitated by applicant's amendments, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn.

Claim 2 and newly added claims 4-7 are currently pending and under examination.

## Election/Restriction

2. Applicant acknowledged the finality of the restriction requirement set forth in the previous Office action mailed 4/24/06, but still maintained the traversal and provided further

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argument with regard to the sequence election requirement. The argument is on the ground that there would be no serious search burden to the Office if "at least ten amino acid sequences" were searched and examined. Applicant maintains that the election of a single amino acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." "The "MPEP further provides," applicant maintains, "that that '[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes."

This is not found persuasive. While the Official Gazette Notice of November 19, 1996 (the basis for the policy articulated in M.P.E.P.) permitted the examiner to waive restriction requirements of 37 CFR 1.141 et seq. and permit a reasonable number of sequences to be claimed in a single application, applicant's attention is drawn to the various important notions and provisos asserted in the policy, e.g. "without creating an undue burden on the Office," "reasonable number of such nucleotide sequences," and "in most cases, up to ten," etc. See MPEP 803.04. It is well recognized that since 1996, when the policy was made, the number of protein and/or nucleic acid sequence databases and the number of sequence entities therein, both for commercial databases and those submitted to the Office, have become astronomically large. As such, due to changes of databases to be searched and the resource allocations at the Office, the ten sequences is no longer a reasonable number of sequences to be examined because it would create a serious undue search burden to the Office.

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## **Priority**

3. With regard to the Office's position set forth in the previous Office action mailed 4/24/06 that priority had not been granted to prior applications 09/684,016 and 09/850,147 because the elected invention, i.e. polypeptide with the sequence of SEQ ID NO:44293, was not found to be adequately disclosed in the prior applications, applicants disagree and "reserve the right to provide evidence that the elected invention is disclosed in the recited applications." However, no such evidence has been provided to the Office.

Applicants further state that "the priority claim has been amended to further include priority as a continuation in part of U.S. Application Serial No. 10/425,115, filed April 28, 2003, which is a continuation-in-part of U.S. Application Serial No. 09/985,678, filed November 5, 2001, which is a continuation of U.S. Application Serial No. 09/304,517, filed May 6, 1999." Applicant is notified that in view of the Petition Decision mailed 11/8/06, priority has not been granted to these prior applications for reasons detailed in the Petition Decision.

#### **Specification**

4. The specification is objected to because of the following:

Trademarks are used in this application, such as ORACLE on page 33. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

It is noted that the specification contains an incorporation-by-reference of the Sequence Listing and Table 1 on compact discs. See page 1. However, the creation date (January 20, 2004)

listed for both the compact disc containing the sequence listing and that containing Table 1 stated in the specification is not consistent with the date (January 27, 2004) as labeled on the compact discs filed 1/29/04. It is thus not clear whether or not contents of the compact discs filed 1/29/04 are meant to be incorporated by reference to the specification.

These objections are reiterated from the previous Office action mailed 4/24/06. Applicant amended the specification in the amendment filed 7/24/06 in an attempt to overcome the objections. However, since the amendments to the specification filed 7/24/06 have not been entered for reasons set forth in section/paragraph 1 above, the objections are maintained.

Appropriate correction is required.

### Claim Rejections-35 USC § 101/§ 112, First Paragraph

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 2 and the newly added claims 4-7 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The rejection of claim 2 is reiterated from the previous Office action mailed 4/24/06, and the rejection of claims 4-7 is newly added, which is necessitated by applicant's amendments filed 7/24/06 that added the new claims.

The amended claims are drawn to a recombinant polypeptide comprising an amino acid sequence of SEQ ID NO:44293, or a sequence that is at least 80%, 85%, 90% or 95% identical with an amino acid sequence of SEQ ID NO:44293. The claimed polypeptide is not supported by

a specific and substantial asserted utility because none of the uses of the polypeptide as disclosed in the specification such as those detailed on pages 10-18, etc. is specific and substantial. For example, the specification states that the claimed recombinant polypeptide is involved in one or more important biological properties in a plant, that such recombinant polypeptide may be produced in transgenic plants to provide plants having improved phenotypic properties and/or improved response to stressful environmental conditions including cold tolerance, and that in some cases, decreased expression of such polypeptide may be desired (see at least page 10). These uses are not specific for the claimed polypeptide comprising a sequence of SEQ ID NO:44293. The specification generically lists a number of possible uses for the multitude polypeptides of SEQ ID NOS: 31565-63128, but fails to assert a specific utility for the claimed polypeptide comprising a sequence of SEQ ID NO:44293, and none of the utilities is specifically linked to the elected polypeptide. Recently, in In re Fisher, a case analogous to the present application, the court held that an asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public and that "Fisher's claimed uses are nothing more than a 'laundry list' of research plans, each general and speculative ... ." In re Fisher, 76 USPQ2d 1225 1229 1230 (CAFC 2005). In the instant application, the list of uses in the specification is akin to such a research plan and does not assert a particular and well-defined benefit to the public for the claimed polypeptide comprising an amino acid sequence of SEQ ID NO: 44293.

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Furthermore, the claimed polypeptide is not supported by a substantial utility. For example, the specification states that the polypeptide can be used for improving stress tolerances, e.g. cold tolerance, in plants, etc. (page 11). However, this utility depends on the

activity/function of the claimed polypeptide, and on the elucidation of the association of cold tolerance therewith, which are yet to be discovered through further research. The apparent need for such research indicates that the claimed polypeptide is not disclosed as to a currently available or substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Also in *In re Fisher*, the court, following an analysis of Nelson, 626 F.2d at 856 with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polypeptide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide comprising an amino acid sequence of SEQ ID NO:44293 such that another non-asserted utility would be well established for the claimed polypeptide.

While it is noted that the specification in Table 1 indicates that the polypeptide of SEQ ID NO:44293 shares sequence homology with the sequence of GENBANK accession number gi29150380, which appears to encode a synaptobrevin-like protein in *Oryza sativa*, one of skilled in the art would have reasonable doubt that the polypeptide of SEQ ID NO:44293 would indeed be a synaptobrevin-like protein for the following reasons:

Firstly, the sequence of gi29150380 is a sequence directly submitted to the GENBANK and the function of the sequence appears to be proposed based on sequence comparisons with other sequences. See the enclosed printout of GENBANK accession No. AAO72389, which is also referred to as gi29150380.

Secondly, it would have been well known in the art that sequence similarity alone does not reliably correlate to identical or even similar biological activities. For example, it would have been well established in the art that even a single nucleotide or amino acid residue change or mutation in a sequence of a biomolecule would be sufficient to destroy the entire function of the biomolecule in many instances. Thus, in the absence of factual evidence characterizing the structural and functional aspects of the biomolecule, the effects of these changes would largely unpredictable as to which ones would have a significant effect and which ones would be silent mutations having no effect. The prior art cannot unambiguously assign function to an unknown gene or protein purely based on sequence homology comparisons. The following example demonstrates that assignment of a known function to a metabolic gene based on homology comparisons alone provides improper and erroneous functional assignment (see the homologybased methods of functional assignment of Everett et al., Nature Genetics 17, 411-422, 1997 in light of the experimental conclusions of Scott et al., Nature Genetics 21, 440-443, 1999). Everett et al. disclose a homology-based functional assignment to a putative, mutated sulfate transporter gene (PDS; which encodes "pendrin") identified through positional cloning in Pendred syndrome populations. The homology-based searches were carried out using BLAST and PSI-BLAST with commercial databases using the human pendrin clone as the query sequence. The conclusions of Everett et al. based upon the homology comparisons were that pendrin was a

transporter of sulfate because it shared sequence homology with known sulfate transporter. The experimental studies by Scott et al., however, clearly demonstrate that pendrin, while having 29% homology to the rat sulfate-ion transporter encoded by Sat-1; 32% homology to the human diastrophic dysplasia sulfate transporter DTD; and 45% homology to the human sulfate transporter down-regulated in adenoma encoded by DRA, is actually not a transporter of sulfate, but rather that of chloride and iodine.

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Thirdly, assuming arguendo that the polypeptide of SEQ ID NO: 44293 were indeed a synaptobrevin-like protein, one skilled in the art would have to perform further research to determine how much its activity/function is "like" synaptobrevin, and what specific and substantial utility the protein might have. It had been known that there were different members of the synaptobrevin protein family. For instance, Raptis et al. (Journal of Chemical Neuroanatomy, Vol. 30, pages 201-211, 2005) disclosed that there were at least two isoforms of synaptobrevins: synaptobrevin/VAMP 1 and synaptobrevin/VAMP 2, which not only have different sequences, different distribution patterns, but also different specialized roles in the neurosecretory process in animals. See Abstract and page 202, left column. Thus, it would require further research to at least determine (1) what exact function the polypeptide of SEQ ID NO:44293 would have, (2) would the protein be like synaptobrevin/VAMP 1 or synaptobrevin/VAMP 2, or both, and (3) how much of its function would be "like" synaptobrevin. Once again, it is clear that the polypeptide of SEQ ID NO:44293 is not disclosed as to a currently available utility.

All the pertinent references based upon in the above rejection have been provided to applicants in the previous Office action mailed 4/24/06.

Applicant's arguments filed 7/24/06 with regard to the above rejection have been fully considered but they are not found persuasive.

Applicant cited a serious of case laws including In re Fisher and argues that the instant specification provides utilities for the claimed polypeptides that are well-defined and provide an immediate benefit to the public. For example, the specification provides that the sequences of the invention can be used for monitoring and modifying synaptobrevin-like protein expression in plants, and that the nucleic acid sequences encoding the synaptobrevin-like protein can be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the reduction or suppression of the endogenous synaptobrevin-like protein. As such, applicant maintains, the instant specification provides specific and substantial utilities for the claimed polypeptide sequence having synaptobrevin-like protein activity. See pages 8-10 of the response.

This is not found persuasive. It is not disputed that one can monitor and/or modify the expression of the synaptobrevin-like protein in plants and that the nucleic acid sequences encoding the synaptobrevin-like protein can be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the reduction or suppression of the endogenous synaptobrevin-like protein. The question is whether such use represents a well-defined utility and provides an immediate benefit to the public, and thus a specific, substantial and credible utility. The answer is "no" because without knowing the exact function/activity of the synaptobrevin-like protein and what possible effect the protein might have on plants' growth, development, overall quality, etc., monitoring and/or modifying the expression of the protein merely represents an invitation for further research because it would be exactly the kind of

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experimentation to be carried out by one skilled in the art to elucidate the exact function of the protein and determine any specific and substantial utility thereof. Therefore, it is clear that this utility is not well-defined and provides no immediate benefit to the public.

Applicant further cites In re Oetiker, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992) and argues that the examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. And applicant cites the Office's Utility Guidelines (Federal Register 66(4): 1096, Utility Guidelines (2001)) arguing that when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion." Applicant alleges that the Office has not provided any support for the apparent proposition that a single example of an alleged improper functional assignment based on homology to a known sequence renders all homology-based functional assignments unreasonable. See page 10-11 of the response.

This is not found persuasive. As set forth in the previous Office action mailed 4/24/06, pages 7-8, and reiterated above, the Office has indeed provided ample scientific reasoning, based on scientific evidence including the "pendrin" example with regard to the unreliability of functional assignment based purely on sequence homology, and the teachings by Raptis et al. with regard to the different isoforms of synaptobrevin with different sequence, different expression pattern and different functions, that functional assignment based on sequence homology alone is not reliable, and one skilled in the art would have reasonable doubt that the

sequence of SEQ ID NO:44293 would have the assigned function. Applicant fails in the response to provide evidence that the scientific evidence and scientific reasoning provided by the Office in the previous Office action is not sound.

Applicant further cites In re Ziegler, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir.1993), In re Brana, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), etc. and argues that the Office has not met its burden and has not assessed the credibility of the presently asserted utilities, and thus the utilities asserted in the specification must be accepted as factually sound. See pages 11-12 of the response.

This is not found persuasive because in the instant application, there is no basis for such a credibility assessment as the presently asserted utilities are neither specific nor substantial for reasons set forth above.

7. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 2 and the newly added claims 4-7 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The rejection of claim 2 is reiterated from the previous Office action mailed 4/24/06, and the rejection of claims 4-7 is newly added, which is necessitated by applicant's amendments filed 7/24/06 that added the new claims.

Applicant's argument filed 7/24/06 has been fully considered but it is not found persuasive. Applicant argues that this rejection has been overcome by the arguments set forth regarding the utility rejection.

This is not found persuasive because the arguments set forth regarding the utility rejection have not been found persuasive for reasons set forth above in section/paragraph 6.

### Claim Rejections-35 USC §112, Second Paragraph

- 9. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 10. Claims 2 and 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is newly added and is necessitated by applicant's amendments to the claims filed 7/24/06.

The amended claim 2 and the newly added claims 4-7 recites "a recombinant polypeptide comprising <u>an</u> amino acid sequence of SEQ ID NO: 44293" or comprising an amino acid sequence having at least about 80%, 85%, 90% or 95% sequence identity with <u>an</u> amino acid sequence of SEQ ID NO: 44,293" (emphasis added by the examiner). The limitation "an amino acid sequence of SEQ ID NO: 44,293" is confusing because the use of the indefinite article "an" suggests that more than one sequences are present in SEQ ID NO: 44,293. However, it is only

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apparent that the full-length sequence of SEQ ID NO: 44,293 is an amino acid sequence of 220 residues long (see the Sequence Listing). It is not clear as to what other sequences are present in SEQ ID NO: 44,293. It is unclear whether it is meant that any fragment of the full-length sequence of SEQ ID NO: 44,293 is also considered as "an amino acid sequence of SEQ ID NO: 44,293."

### Claim Rejections-35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 12. Claims 2 and 4-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, September 6, 2000).

This rejection is newly added, which is necessitated by the amendments filed 7/24/06.

The claims are drawn to a recombinant polypeptide comprising an amino acid sequence of SEQ ID NO:44293, or a sequence that is at least 80%, 85%, 90% or 95% identical with an amino acid sequence of SEQ ID NO:44293.

Alexandrov et al. disclose multiple polypeptides including a polypeptide, a *Zea mays* polypeptide, comprising an amino acid sequence that shares a 99.5% overall match with the full-length sequence of the instant SEQ ID NO:44293. See the sequence alignment between SEQ ID

NO:44293 and the sequence of database Geneseq accession number AAG44786, which is the same sequence as that of SEQ ID NO:56142 disclosed by Alenxandrov et al.

As to claim 2, given the indefiniteness of the claim set forth above in section/paragraph 10, it is interpreted that the claim is drawn to a polypeptide comprising any fragment of SEQ ID NO:44293 that is two or more amino acid residues long, which is interpreted as being "an amino acid sequence of SEQ ID NO:44293" recited in the claim. The polypeptide disclosed by Alexandrov et al. comprises a sequence that is 100% identical with a sequence of 107 amino acid residues long: from residue number 1 to residue number 107 of SEQ ID NO:44293. See the sequence alignment between SEQ ID NO:44293 and the sequence of database accession number AAG44786. See at least pages 327-328 for the production of recombinant proteins/polypeptides.

13. Claim 2, and the newly added claims 4-7 are rejected under 35 U.S.C. § 102(e) as being anticipated by La Rosa et al. (US 20040214272 A1, published application of 10/425,115).

The rejection of claim 2 is reiterated from the previous Office action mailed 4/24/06, and the rejection of claims 4-7 is newly added, which is necessitated by applicant's amendments filed 7/24/06, which added the new claims.

La Rosa et al. disclose a polypeptide with a sequence that is 100% identical with the full-length sequence of SEQ ID NO:44293 in the instant application. The polypeptide can be produced with recombinant polynucleotide by recombinant technology and is thus a recombinant polypeptide. See the attached sequence alignment between SEQ ID NO:44293 and SEQ ID NO: 193538. Also see paragraphs 0006, 0019, 0033, 0035, 0037, and 0066 of La Rosa et al.

Documents based upon in this rejection have been provided to applicants in the previous Office action mailed 4/24/06.

Applicant's argument filed 7/24/06 has been fully considered but it is not found persuasive. Applicant argues that this rejection should be withdrawn because applicant amended

the priority claim of the instant application that claims priority to the prior application 10/425,115, which is the basis of this rejection.

This is not found persuasive because as set forth above and in the Petition Decision mailed 11/8/06, priority to the prior application 10/425,115 has not been granted for reasons set forth in the Petition Decision.

## Withdrawn Rejections

14. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite, set forth in the previous Office action, mailed 4/24/06, page 9, is hereby withdrawn in view of applicant's amendment to the claim filed 7/24/06.

#### Conclusion

- 15. No claim is allowed.
- 16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 17. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136
- (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be

calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

sz/SZ

SHUBO (JOE) ZHOU, PH.D. PATENT EXAMINER